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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/547,068

09/26/2006

Spiros Fotinos

1581/140

5149

2101 7590 06/04/2010
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BOSTON, MA 02110-1618

EXAMINER

BARHAM, BETHANY P

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

06/04/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/547,068	Applicant(s) FOTINOS ET AL.	
	Examiner BETHANY BARHAM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 113 and 115-148 is/are pending in the application.
- 4a) Of the above claim(s) 115-118 and 126-146 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 113, 119-125, 147 and 148 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/01/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of Applicant's response and claim amendments filed on 03/17/10 are acknowledged. The IDS filed on 02/01/10 is also acknowledged. Claims 113 and 115-148 are pending; and claims 115-118 and 126-146 remain withdrawn. Claims 113, 119-125 and 147-148 are rejected.

Due to Applicant's claim amendments the previous objections and rejections are hereby withdrawn.

NEW REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 113, 119-120, 122, 124-125 and 147-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0160035 ('035) in view of WO 97/20549 ('549) or US 5,453,296 ('296) and US 5,071,704 ('704).

The instant claims are drawn to a patch having reduced adhesion for delivering a volatile substance, the patch comprising: an active layer comprising the volatile

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substance; a barrier layer having a first side and an opposite side, the first side attached to the active layer; a fractional adhesion layer adjacent to an opposite side of the barrier layer from the active layer, the fractional adhesion layer comprising an adhesion area that is a fraction of the total area of a side of the barrier layer, wherein the fraction is less than 1; and a release liner covering the adhesion area adjacent to the opposite side of the barrier layer.

- '035 teaches a patch that delivers a volatile substance and Fig 1 teaches a volatile active layer (3), a barrier layer (4), an adhesive layer (2), and a release liner (5), wherein the release liner cover the adhesive layer which is next to (or adjacent) the barrier layer with the active on the other side of the barrier layer (abstract, Fig 1, [0038-0039, 0041-0042, 0046-0047]) (meeting the limitations of claim 113). From Fig. 1 it can be seen that the barrier layer (4) is sandwiched in between the adhesive layer (2) and the active layer (1).
- '035 teaches that the active layer is a solid and contains polymers like gelatin, hydroxypropylcellulose, etc [0011, 0051, 0055] (meeting the limitations of claim 119).
- '035 teaches volatile substances include insect repellent, deodorizers, aromatherapy, essential oils, etc [0018, 0030] (meeting the limitations of claim 122).
- '035 does not teach that the adhesive layer has a fraction less than 1 or is discontinuous or dots of instant claims 1 and 147-148.

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- '549 teaches a patch with an adhesive layer in a ring formation and as seen from Figs. 1-3 the adhesive does not cover the entire patch and according to '549 it is discrete or forms a ring on a portion of the patch (pg. 3).
- '296 teaches a product with adhesive dots (**10**) that are present on a portion of the barrier layer Figs. 1-2, 4 and 5b-5c (note: the adhesive does not cover the entire product) (according to the limitations of claims 113 and 147-148).
- '035, '549 or '296 do not teach a polyurethane reservoir layer or a high specific surface area instant claims 119-120 and 124-125.
- '704 a controlled release device that is multilayered with i) a reservoir layer containing the active, ii) an impermeable membrane layer and iii) an adhesive layer teaches that the reservoir layer contains a porous polymer or foam with cell sizes with a porosity from about 0.1-0.8, such as polyurethanes and that the active compound and polymer can form a system where the particulates of the compound are dispersed throughout the polymer (col. 4, lines 30-43; col. 7, lines 50-col. 8, lines 11) (meeting the limitations of instant claims 119-120 and 124-125).
- Note giving the claims the broadest reasonable interpretation the prior art teaching of a porous, or foam with cell sizes and porosity from about 0.1-0.8 reads on the instant claims "high specific surface area" and "bubbles" as instant claimed in claims 124-125.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '035 and '549 or '296 with '704. A skilled artisan would know

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how to substitute the discontinuous/dot adhesive of '549 or '296 into the product of '035 containing an adhesive layer with predictable results. The simple substitution of one adhesive layer '035 for another of '549 or '296 that is discontinuous/dots is within the purview of the skilled artisan and would yield predictable results.

Further, a skilled artisan would know how to substitute the polyurethane reservoir layer of '704 into the product of '035 with the adhesive of '549 or '296 containing a reservoir layer with predictable results. The simple substitution of one reservoir layer '704 for another of '035 is within the purview of the skilled artisan and would yield predictable results.

Lastly a skilled artisan would know how to rearrange the known components of '035 (active, barrier, adhesive and release liner layer attached to the adhesive layer) via the known technique of '704 which teaches arranging multilayered patch to include i) a reservoir layer containing the active, ii) an impermeable membrane layer and iii) an adhesive layer with the release liner of '035 with predictable results. The combination of a known technique with a known product ready for improvement is within the purview of the skilled artisan and would yield predictable results.

Claims 113, 119-122 and 124-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0160035 ('035) in view of WO 97/20549 ('549) or US 5,453,296 ('296) and US 5,071,704 ('704) and further in view of US 2003/0007944 ('944) or US 2003/0118533 ('533).

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- '035, '549 or '296 and '704 are taught above (meeting the limitations of claims 113, 119-120, 122, 124-125 and 147-148).
- '035, '549 or '296 and '704 do not teach polyurethane-1 of instant claim 121, but '704 does teach the reservoir layer containing a polyurethane.
- '944 teaches film forming compositions for application to the skin containing polyurethane, preferably polyurethane-1 (abstract) (meeting the limitations of claims 121).
- '533 teaches topical compositions for patches including polymers such as Luviset or polyurethane-1 [0023, 0026].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the specific polyurethane-1 of '944 or '533 into the reservoir layer of '704 and further into the product of '035, '549 or '296 and '704 with predictable results. Simple substitution of one polyurethane of '704 for another of '944 or '533 is within the purview of the skilled artisan and would yield predictable results.

Claims 113, 119-120, 122-125 and 147-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0160035 ('035) in view of WO 97/20549 ('549) or US 5,453,296 ('296) and US 5,071,704 ('704) and further in view of US 5,589,122 ('122) or US 6,129,983 ('983).

- '035, '549 or '296 and '704 are taught above and teach a patch for the release of vapors or liquid which is multilayered with a reservoir layer containing the active such as a perfume, fragrance, insect repellent, a diffusion/barrier/controlled

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release layer, an adhesive layer and an impermeable membrane (abstracts) (meeting the limitations of claims 113, 119-120, 122, 124-125 and 147-148).

- '035, '549 or '296 and '704 do not teach "the barrier layer is a double coated tape, each side of the double coated tape covered with an adhesive layer" of instant claim 123, but do a diffusion/barrier/controlled release layer.
- '122 teaches double-sided adhesive tape which has adhesive layers on two sides, typically with a layer in between the adhesive tapes and the method of making such tapes (abstract, col. 1, lines 13-15; col. 2, lines 43-55; Fig. 1).
- '983 teaches a double-sided self-adhesive tape comprising a layer that is coated on both sides with adhesive compositions and methods of making such double-sided tapes (abstract, col. 3, lines 62-col. 4, lines 18)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the known method of making a layer comprising a double sided adhesive tape of '122 or '983 into the known multilayered patch compositions of '035, '549 or '296 and '704. Combination of a known product (ie patch) of "035, '549 or '296 and '704 with a known technique (ie a method of making a layer a double-sided adhesive tape) of '122 or '983 is within the purview of the skilled artisan and would yield predictable results.

Response to Arguments

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Applicant's arguments with respect to claims 113, 119-125 and 147-148 have been considered but are moot in view of the new grounds of rejection which were partly necessitated by applicants' amendments.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham
Art Unit 1615

/S. TRAN/
Primary Examiner, Art Unit 1615